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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

ACSES 56001 (2636P)

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on March 2, 2007

Signature

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name

THOMAS H. MAJCHER

Application Number

09/897,295

Filed

June 29, 2001

First Named Inventor

William J. Boyle

Art Unit

3743

Examiner

Teena Kay Mitchell

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒ attorney or agent of record.Registration number 31,119☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34

Signature

THOMAS H. MAJCHER

Typed or printed name

310 824 5555

Telephone number

MARCH 2, 2007

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.



*Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Thomas H. Majcher
Thomas H. Majcher, Reg. No. 31,119



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 09/897,295
Applicant : William J. Boyle et al.
Filed : June 29, 2001
Title : DELIVERY AND RECOVERY SHEATHS
FOR MEDICAL DEVICES
Art Unit : 3743
Examiner : Mitchell, Teena Kay

Docket No.: : ACSES 56001 (2636P) Los Angeles, California
Customer No. : 24201 March 2, 2007

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Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention is directed to delivery and recovery sheaths for use with medical devices which deliver self-expanding medical devices, such as stents and vascular grafts, for implantation in a patient's vasculature. The present invention can be used with other medical devices, such as an embolic filtering device, which generally includes a self-expanding filter basket disposed on a guide wire. The restraining device of the present invention can be used to deliver the filtering device or stent to the target location in the patient's anatomy and/or to collapse and retrieve the filtering device once the interventional procedure has been completed.

The restraining device includes a restraining sheath having an expandable housing portion adapted to collapse and hold the self-expanding medical device. The expandable housing portion is made from an elastic material to hold the medical device in place and prevent premature deployment. The housing portion of the sheath acts to "encapsulate" the medical device, thus preventing it from being released from the sheath until the physician is ready to do so. When the present invention is utilized as a recovery sheath to recover a filtering device, the housing portion will contract to its smallest diameter as it tracks along the guide wire to reach the embolic filtering basket. As a result, the tip of the sheath should not scrape the walls of the body vessel causing a "snowplow" effect as the sheath is being advanced over the guide wire. Once the filtering basket is retrieved, the elasticity of the housing portion encapsulates the basket to prevent emboli trapped in the basket from "back washing" into the patient's vasculature.

The expandable housing portion includes one or more reinforcing members that provide additional column strength to the housing portion but do not interfere with the radial expansion or contraction of the elastic housing. These reinforcing members provide additional column strength which permits the housing portion to be made from a highly elastic material that would otherwise buckle when subjected to an applied axial force. Various configurations of this reinforcing member are recited in the dependent claims.

NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of September 11, 2006 is being filed concurrently herewith along with the appropriate fee.

ISSUES ON APPEAL

At issue is whether claims 3-13, 20-26 and 41-51 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent") in view of U.S. Patent No. 6,123,715 to Amplatz (the "Amplatz patent") and U.S. Patent No. 6,517,765 to Kelley (the "Kelley patent").

The Hopkins patent discloses a retrieval sheath including an expandable housing portion used to retrieve a filter. The Examiner has taken the position that the Hopkins patent discloses a housing portion made primarily from an elastic material which is movable between a contracted position and expanded position, but has admitted that the Hopkins patent fails to disclose a

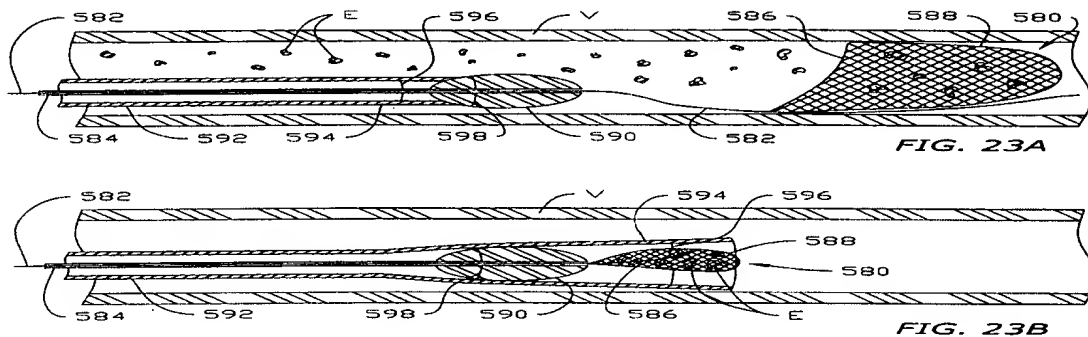
reinforcing member which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion. All of the pending claims include the recitation of a reinforcing member. The Amplatz patent simply discloses a method for forming intravascular devices using a resilient metal fabric. The Examiner relies on a statement appearing in the Amplatz patent that describes the metal fabric used in the Amplatz method as being a tubular braid that has been used in the medical device field to reinforce the walls of guiding catheters (See Column 3, lines 39-48 of the Amplatz patent). The Kelley patent is directed to a method for fabricating flexible and reinforcing tubing and simply teaches that the pitch and/or braid pick counts of the woven fabric and braid can be selected to affect the flexibility of the tubing into which they are formed. The Examiner has taken the position that it would have been obvious to modify the expandable housing portion of the Hopkins device by adding the woven braids disclosed in the Amplatz and Kelley patents. However, Appellant submits that the housing portion disclosed in the Hopkins patent already possesses sufficient column strength and that there would be no need or reason to utilize reinforcing members to increase column strength of the tubing used to form the housing.

A copy of the pending claims is attached hereto as Exhibit A. A copy of the drawings is attached hereto as Exhibit B. A copy of the final Office Action dated September 11, 2006 is attached hereto as Exhibit C. A copy of the Advisory Action dated January 4, 2007 is attached hereto as Exhibit D. A copy of the Hopkins patent is attached as Exhibit E. A copy of the Amplatz patent is attached as Exhibit F. A copy of the Kelley patent is attached as Exhibit G.

ARGUMENT

Claims 3-13, 20-26 and 41-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and the Kelley patent. The Examiner relies on the embodiment of Figures 23A and 23B in the Hopkins patent as the primary reference. First, it is noted that the retrieval sheath **592** and expandable end region **594** (the housing portion) of the Hopkins device already possesses sufficient column strength as evidenced when the expander **590** moves into the end region **594** to radially expand it in order to form a larger opening to retrieve the filter **580**.

Figures 23A and 23B of the Hopkins patent, relied upon by the Examiner in rejecting the pending claims, are reproduced herein.



Reference is initially made to Figure 23B of the Hopkins patent which clearly shows that the distal end region **594** of the retrieval sheath **592** remains "unbunched" after being radially stretched by the expander **590**. The end region **594** of the retrieval sheath **592** must possess sufficient column strength in order to allow the expander **590** to move within the opening to radially expand the tubing. Otherwise, if the end region **594** did not possess enough column strength, then the end region **594** would "bunch" upon itself, much like the bellows of an accordion, when the expander **590** contacts the end region **594** and applies an axial force.

The Hawkins patent thus fails to disclose the use or need for **any** reinforcing member with its housing since the housing already has sufficient column strength to retrieve the filter **580**. The sheath **592** already possess sufficient column strength as evidenced by the expander's ability to radially expand the end region **594** without causing bunching. If the end region **594** did not possess sufficient column strength, then the expander **590** would crush the tubing longitudinally as the expander **590** is drawn into the end region **594**. Therefore, one skilled in the art would see no need or reason to increase the column strength of the Hopkins retrieval sheath **592** with any type of reinforcing member.

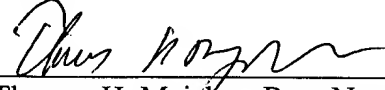
Even assuming *arguendo* that one would still want to increase the column strength of the Hopkins sheath **584**, claims 1 and 41 require the reinforcing member to increase the column strength of the housing portion without interfering with the expansion or contraction of the housing. The Amplatz patent simply teaches that woven braids have been used to reinforce the walls of a guiding catheter. Guiding catheters are generally designed to be laterally flexible and will revert to a pre-formed shape to position a catheter in the patient's vasculature. In this regard,

the guiding catheter will be inserted into the patient's vasculature in a relative linear configuration and will revert to its pre-formed shape after reaching its target location. This requires flexibility along the length of the guiding catheter, but not radial expandability, since the tubular structure of the guiding catheter is not designed to expand radially. For this reason, tubular braids have been used to reinforce the wall of the guiding catheter since the intertwining braid geometry is designed to inhibit expansion, but allows lateral or longitudinal flexibility. Simply put, the use of a woven braid with an expandable housing would inhibit radial contraction and expansion of the housing.

The sheath in the Hawkins patent is designed to radially expand as it contacts the expander. However, a woven braid placed on or into an expandable sheath would inhibit the sheath from expanding or contracting radially. The Kelley patent merely teaches that the pitch and/or braid pick counts of the woven braid can be selected to affect the flexibility of the tubing into which they are formed. Therefore, lateral flexibility can be changed. However, woven braids or fabrics generally inhibit expansion or contraction of tubing. Therefore, while one can increase or decrease the lateral flexibility of the tubing by varying the pitch or braid count, the woven braid or fabric still inhibits expansion and contraction of tubing. Therefore, the combination of the Hopkins patent with either the Amplatz or Kelley patent fails to create the structure recited in the pending claims.

In summation, the Hopkins patent fails to disclose the basic elements recited in the pending claims. Moreover, there would be no need or reason to add reinforcing members to the Hopkins sheath. The Amplatz and Kelley patents only disclose structure which would inhibit expansion and contraction of the housing portion.

Respectfully submitted,
FULWIDER PATTON LLP

By: 
Thomas H. Majcher, Reg. No. 31,119

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201
157274.1

3. (Previously Presented) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position and expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is movable between the contracted position and expanded position and includes at least one reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

4. (Previously Presented) The restraining device of claim 3, further including:
a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:
the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:
the reinforcing members are elongated bar-like members made from a material having high stiffness.

7. (Original) The restraining device of claim 3, wherein:
the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX.

8. (Previously Presented) The restraining device of claim 4, wherein:
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.

9. (Previously Presented) The restraining device of claim 8, wherein:
the reinforcing members are loaded with a material having high radiopacity.
10. (Previously Presented) The restraining device of claim 3, wherein:
the expandable housing portion is made from a substantially tubular-shaped
material which is highly elastic and includes a plurality of reinforcing members disposed within
the tubular elastic material to provide additional column strength to the housing portion.
11. (Previously Presented) The restraining device of claim 4, wherein:
the reinforcing members are disposed within the elastic material forming the
expandable housing portion.
12. (Previously Presented) The restraining device of claim 4, wherein:
the reinforcing members are attached to the surface of the expandable housing
portion.
13. (Previously Presented) The restraining device of claim 4, wherein:
each reinforcing member is disposed along the expandable housing portion to
provide additional column strength to the housing portion but does not interfere with the
expansion of the housing portion.
- 14-19. (Withdrawn)
20. (Previously Presented) The restraining device of claim 3, wherein:
the expandable housing portion includes a low expansion section with at least one
expansion member disposed within the low expansion section to provide the elasticity needed to
move the housing portion between the contracted position and expanded position.
21. (Previously Presented) The restraining device of claim 3, wherein:
the expandable housing portion includes a plurality of low expansion sections and
a plurality of expansion members disposed between low expansion sections.

22. (Original) The restraining device of claim 21, wherein:
the low expansion sections are made from a material loaded with a material having high radiopacity.
23. (Original) The restraining device of claim 21, wherein:
the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBAX.
24. (Original) The restraining device of claim 23, wherein:
the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.
25. (Original) The restraining device of claim 21, wherein:
the expansion members extend longitudinally along the length of the expandable housing portion.

26. (Original) The restraining device of claim 25, wherein:
the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.

27-32. (Withdrawn)

33-40. (Canceled)

41. (Previously Presented) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:
a restraining sheath having an expandable housing portion adapted to move between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a reinforcing member associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed

condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.

42. (Previously Presented) The restraining device of claim 41, further including:
a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.

43. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is embedded in the wall which forms the expandable housing portion.

44. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.

45. (Previously Presented) The restraining device of claim 41, wherein:
the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAX.

46. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.

47. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is loaded with a material having high radiopacity.

48. (Previously Presented) The restraining device of claim 41, wherein:
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.

49. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is molded within the material used to form the
expandable housing portion.
50. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is attached to the surface of the expandable housing
portion.
51. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member helps to bias the expandable housing portion in the
contracted position.

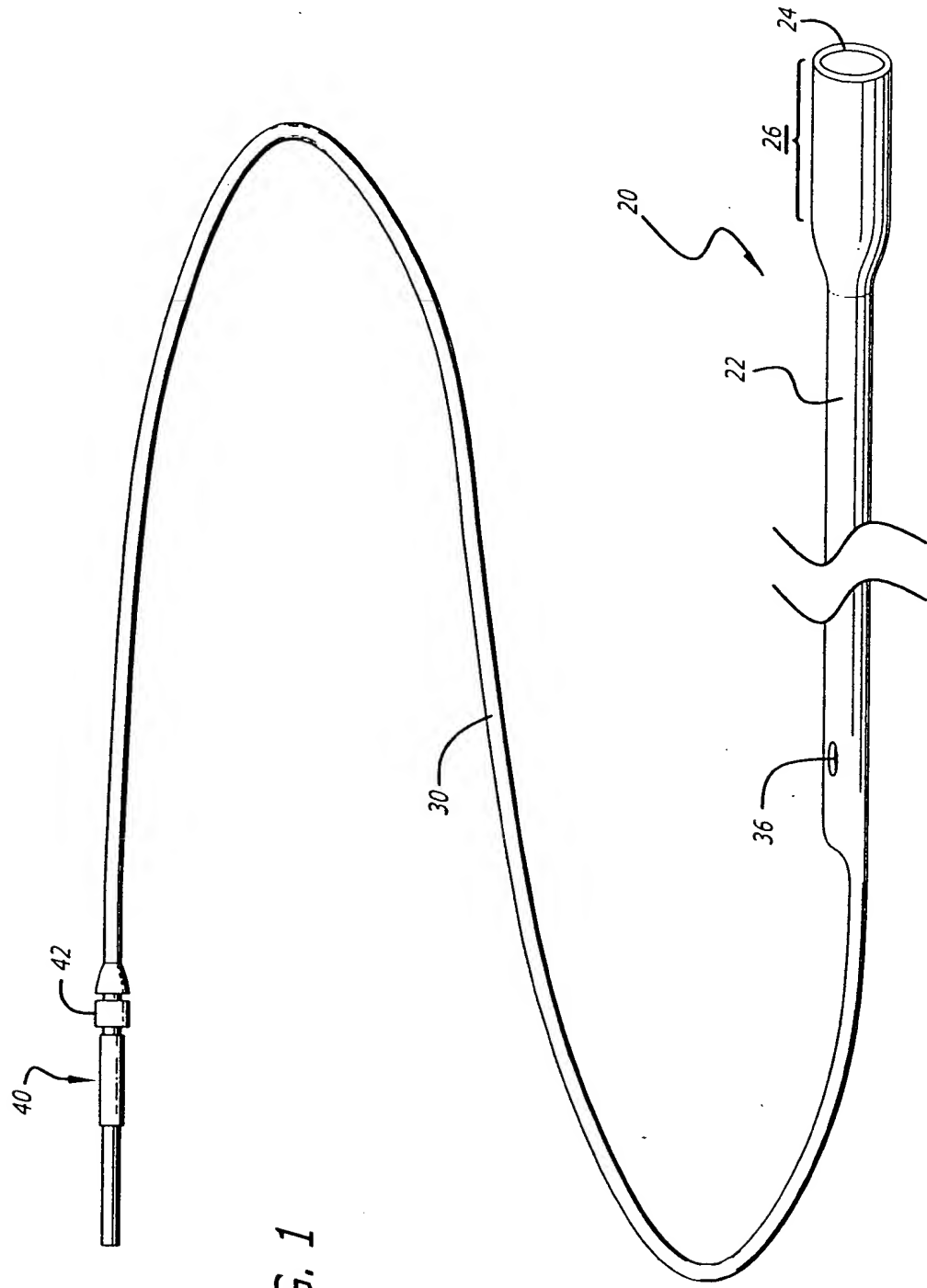


FIG. 1

FIG. 2

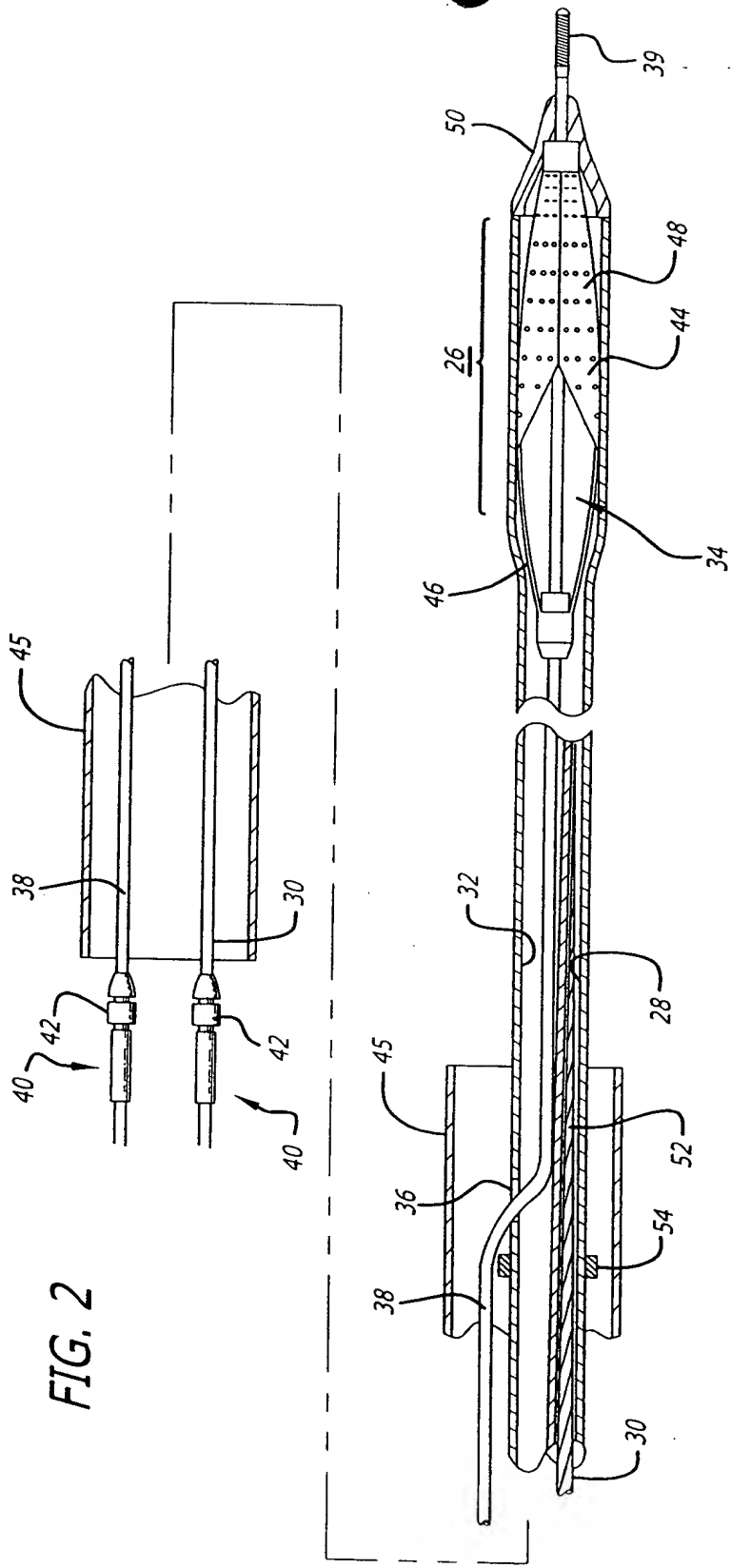
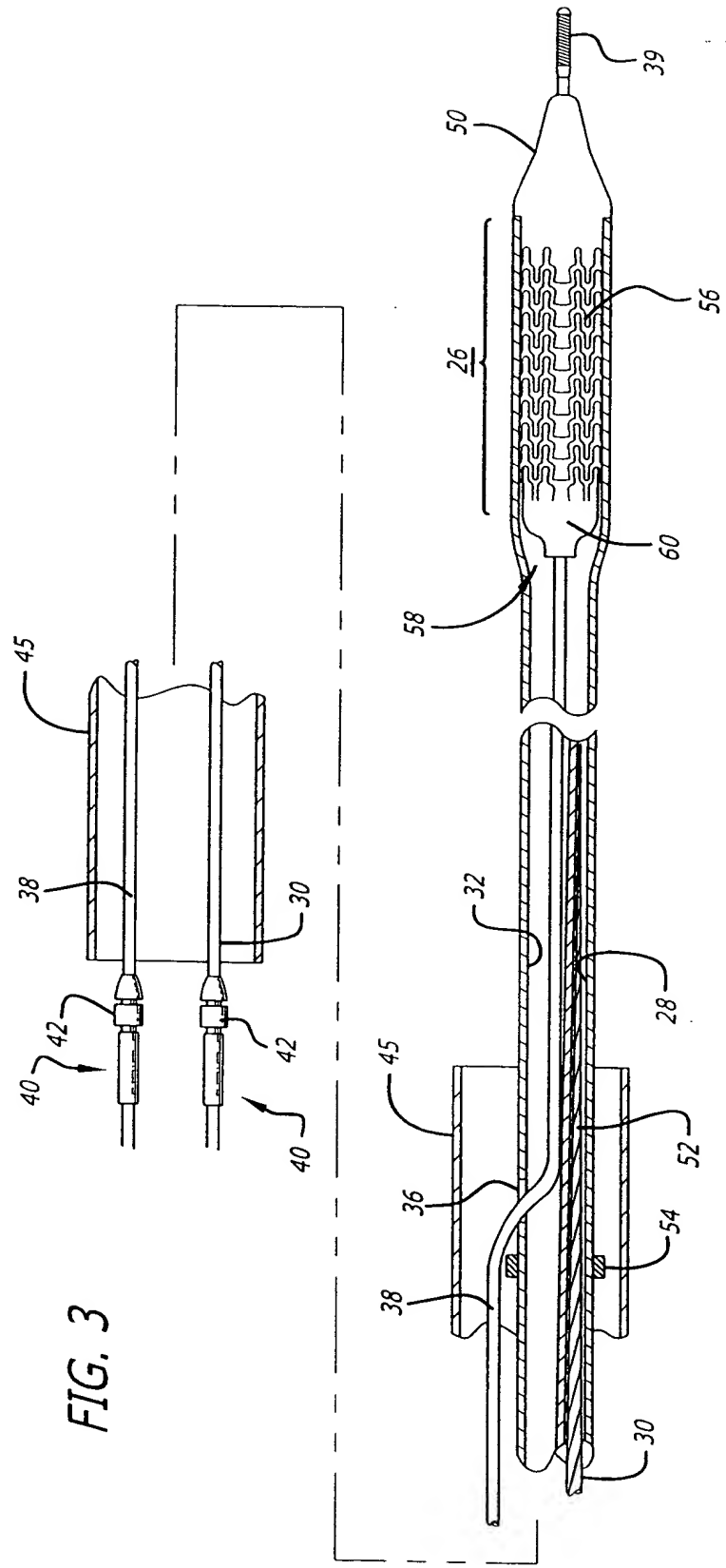
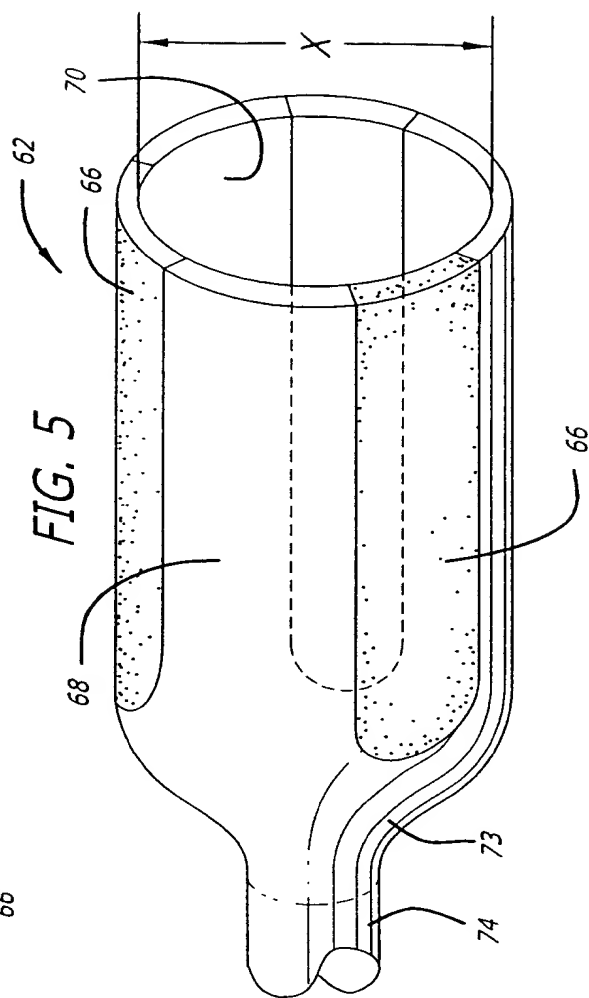
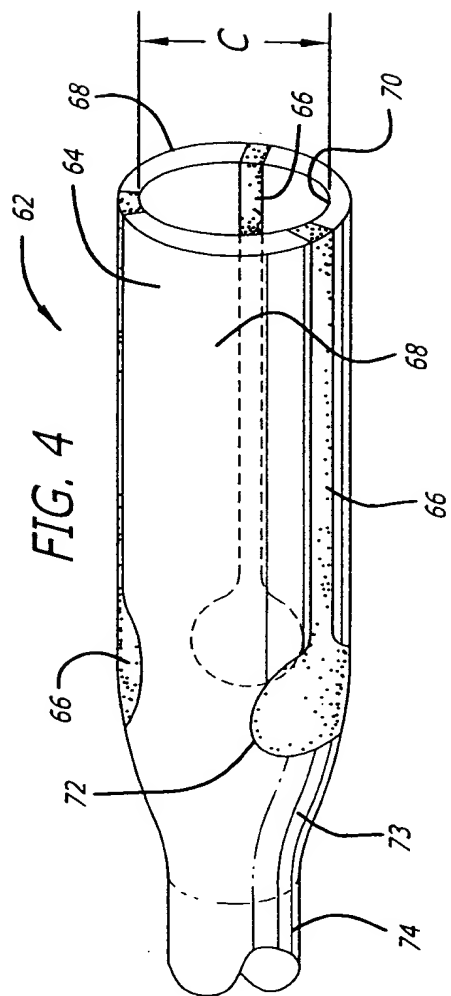
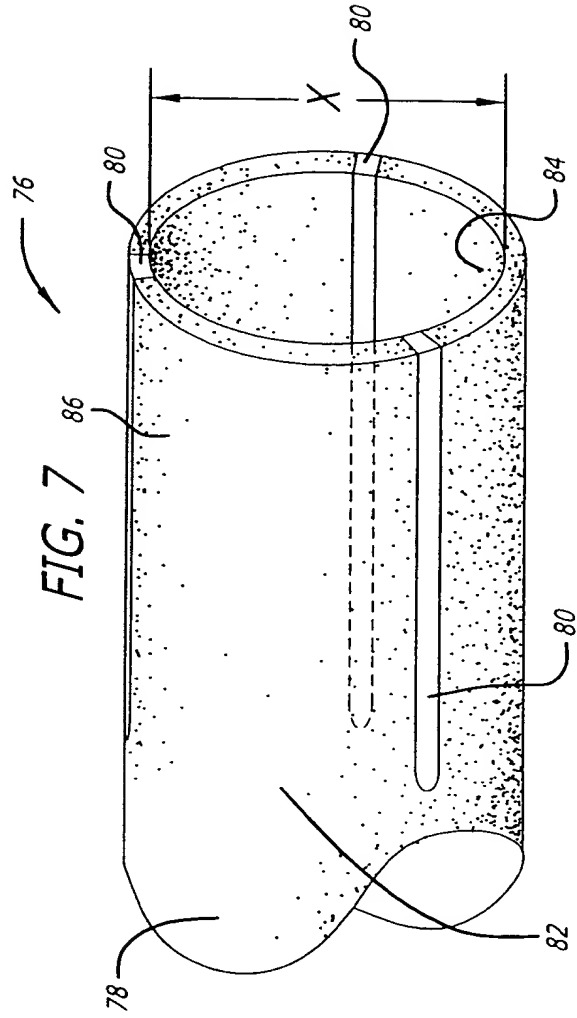
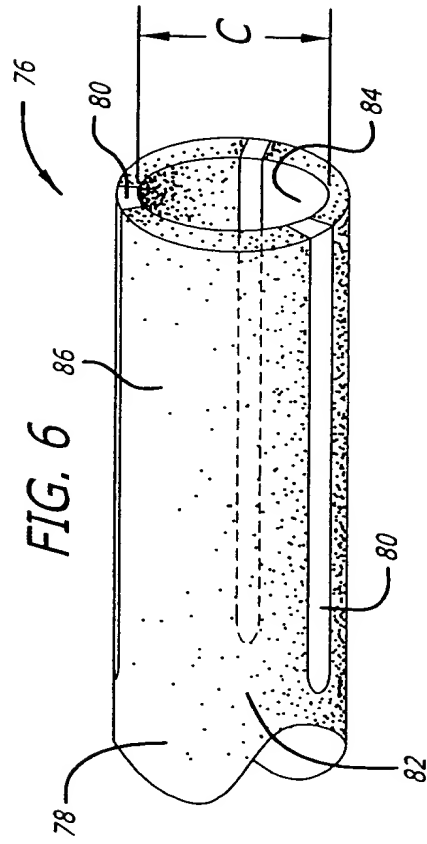
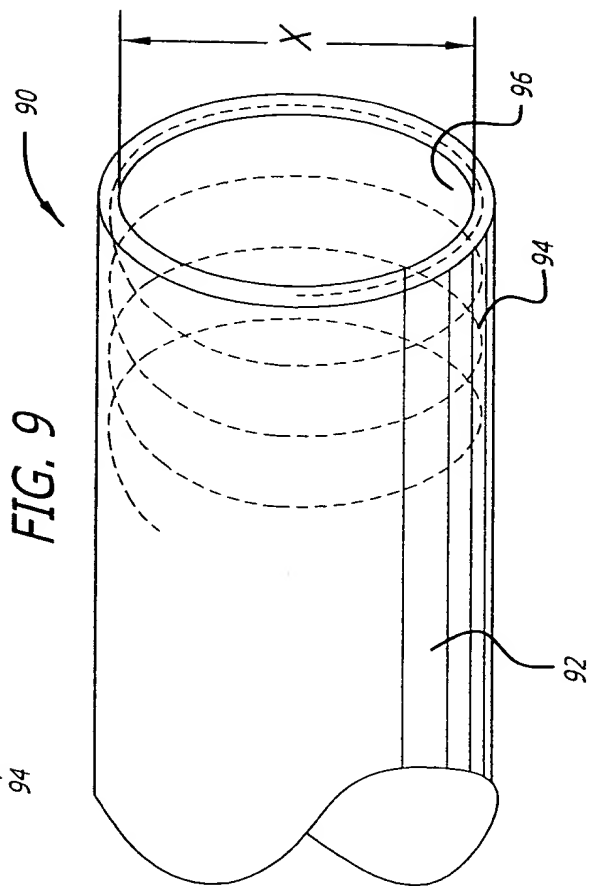
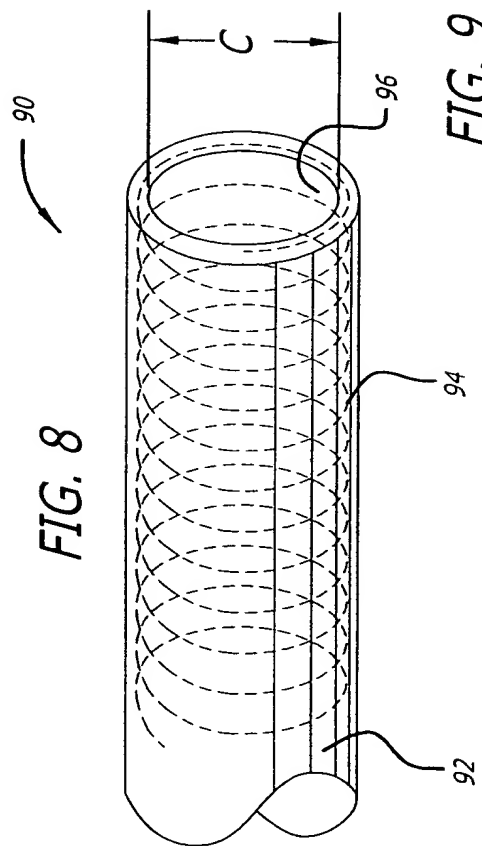


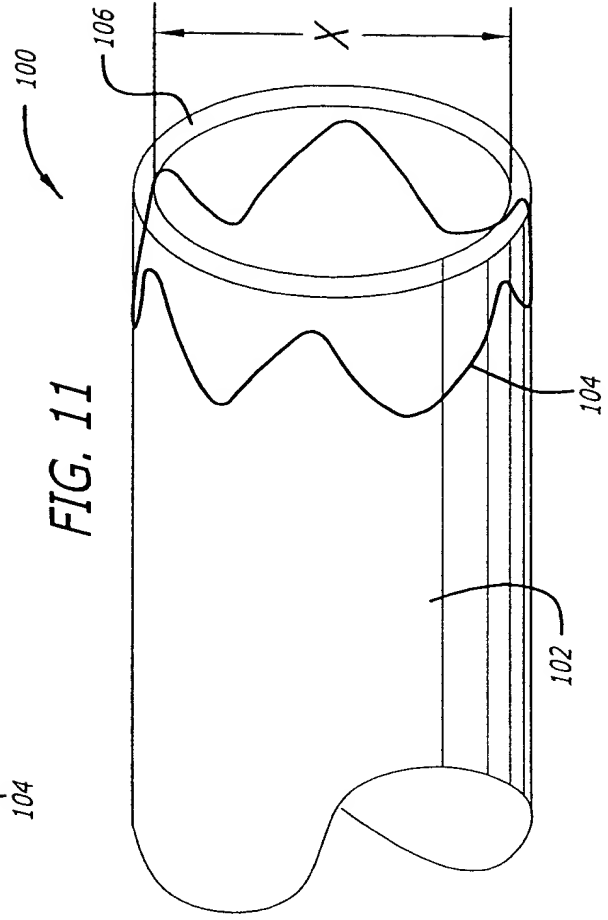
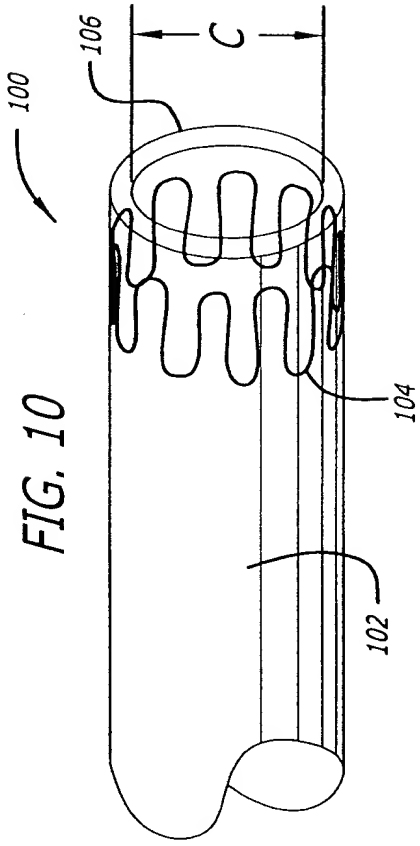
FIG. 3

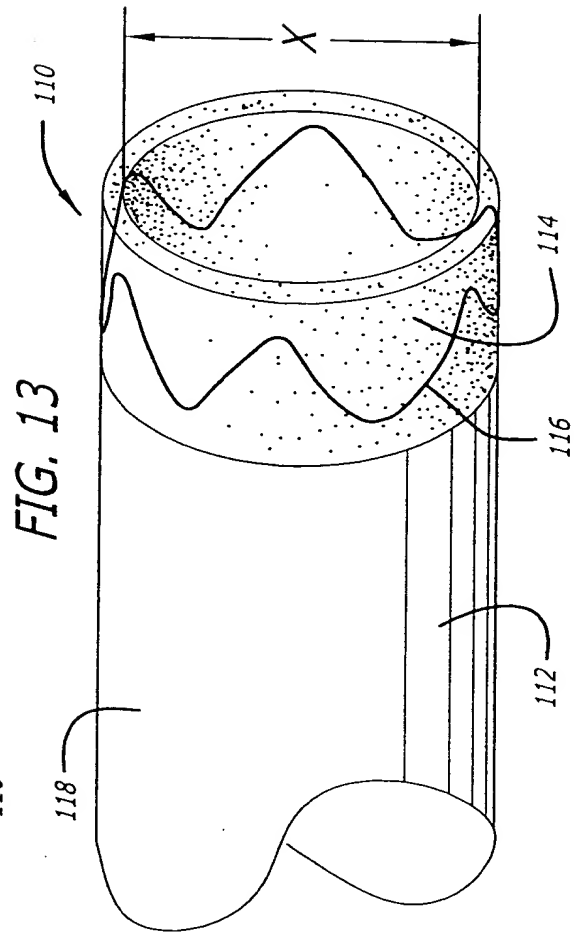
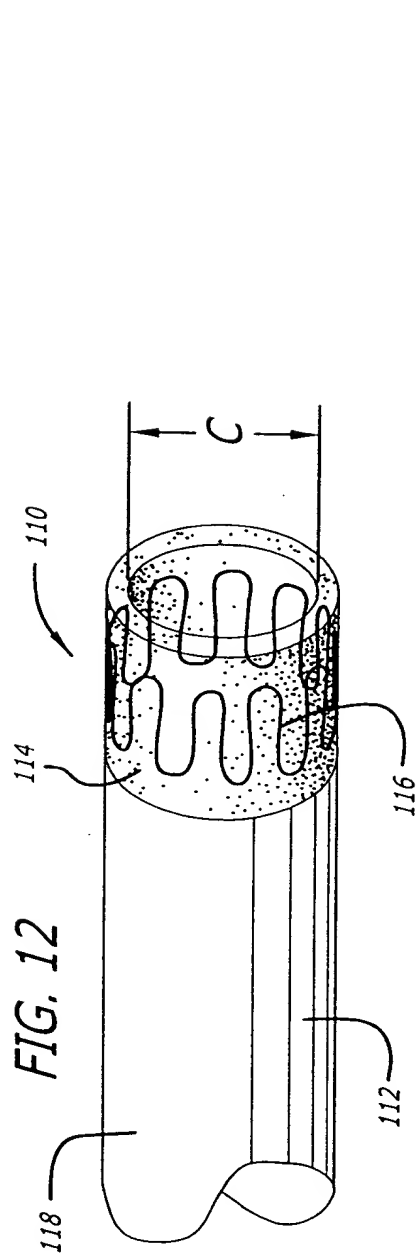


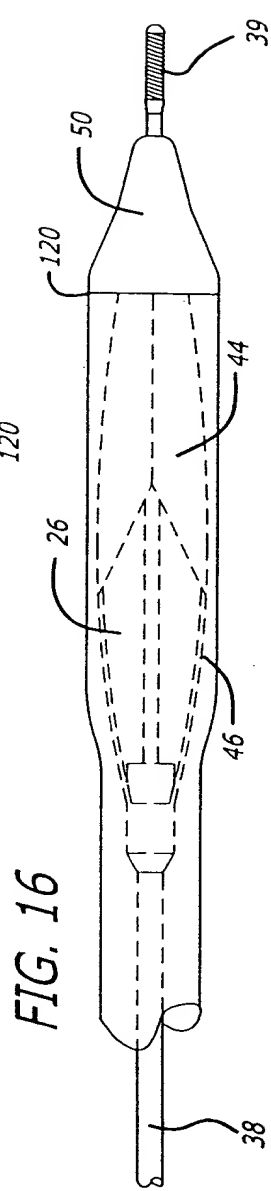
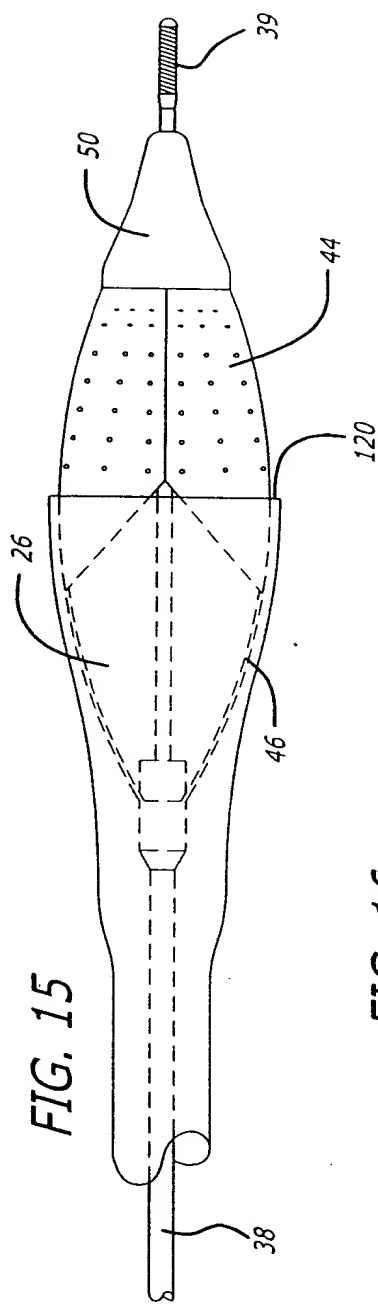
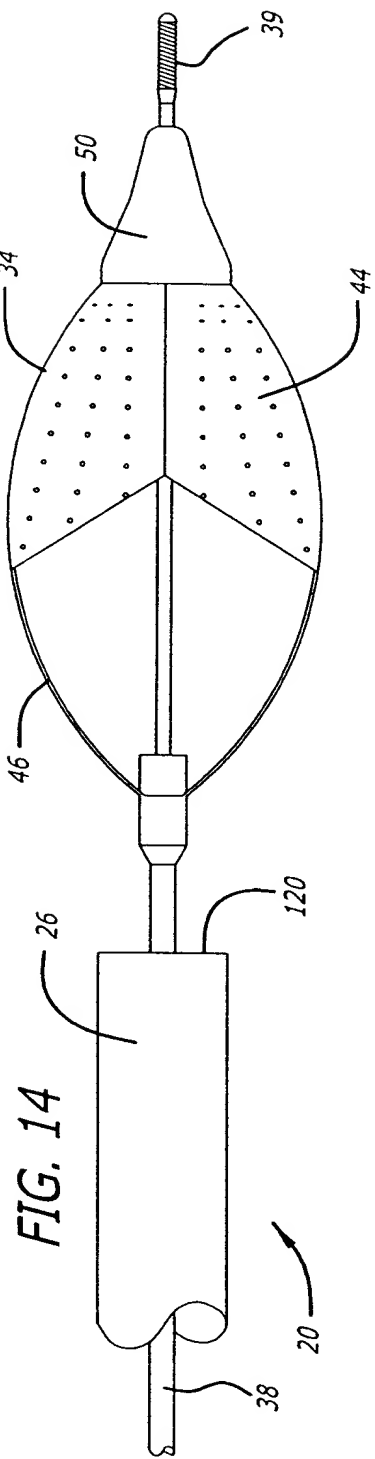












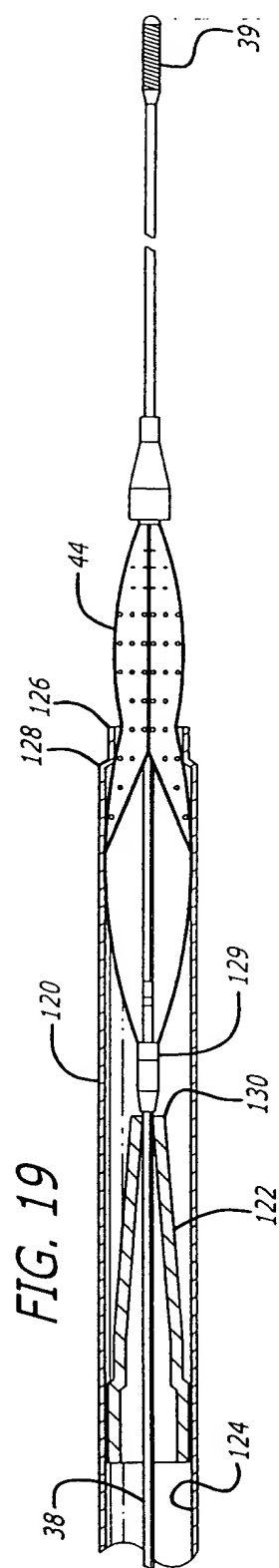
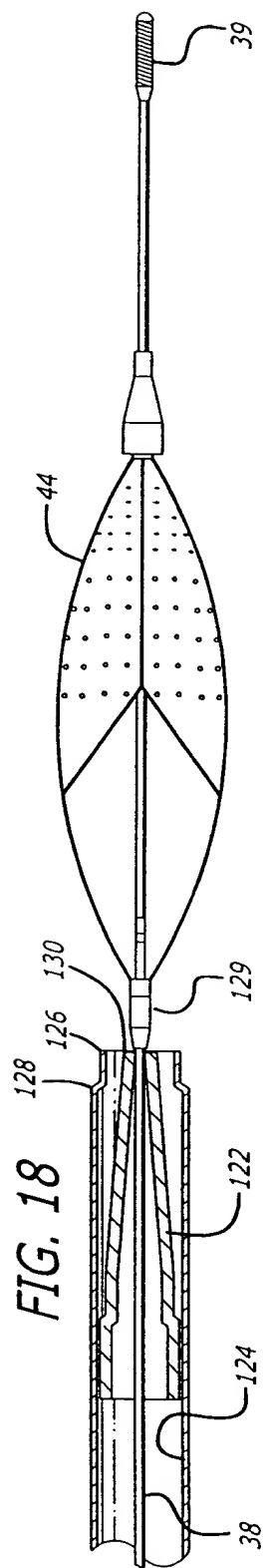
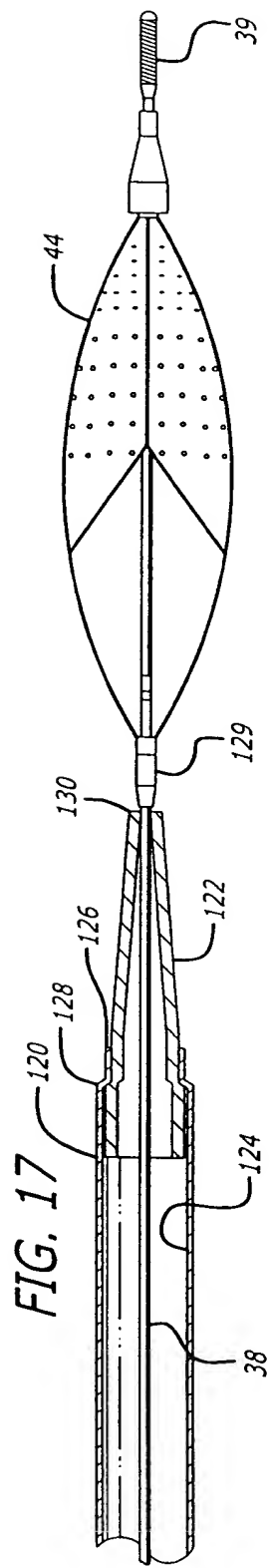


FIG. 20

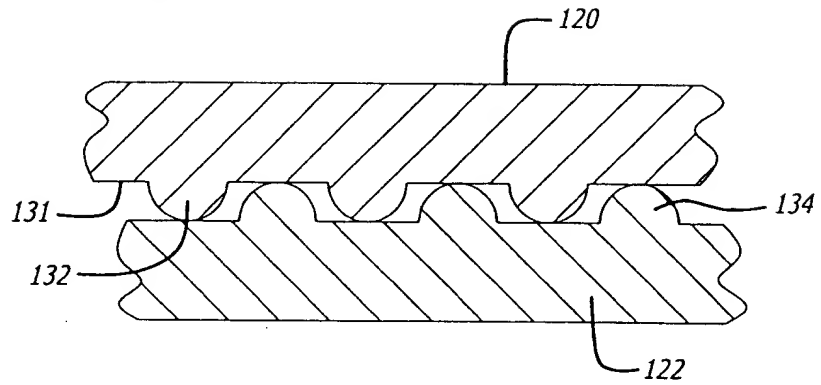
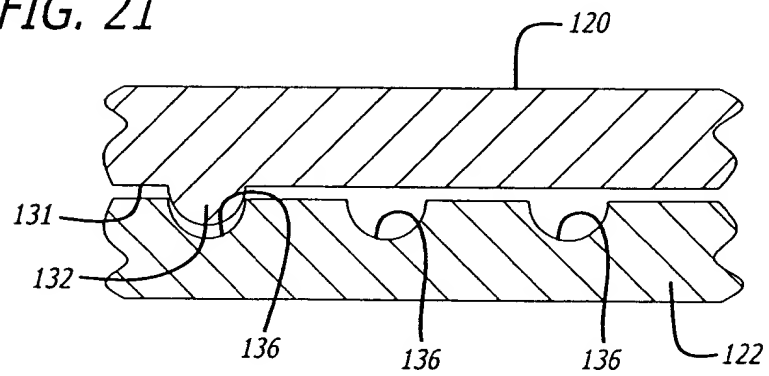


FIG. 21





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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994
24201	7590	09/11/2006	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,295

Applicant(s)

BOYLE ET AL

Examiner

Teena Mitchell

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-32 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-13, 20-26, 41-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-13, 20-26, 41-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of "...non-woven reinforcing member..." which was not previously presented in the originally filed specification constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 3-13, 20-26, and 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et.al. (6,544,279) in view of Amplatz (6,123,715) and Kelley (6,517,765).

Hopkins in a restraining device discloses a restraining sheath having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588) in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position (Fig. 23A) and an expanded position (Fig. 23B), the housing portion having sufficient column strength to maintain the self-expanding medical device (588) in its collapsed condition on its delivery device, wherein the expandable housing portion (594) is made primarily from an elastic material which is movable between the contracted position and expanded position. With respect to the limitation of the reinforcing member being non-woven, Hopkins does not teach a non-woven. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member be a non-woven, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the reinforcing member being a non-woven provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz

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to obtain the invention as specified in claim 3 with the reinforcing member being a non-woven

The difference between Hopkins and claim 3 is a reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

Amplatz in an intravascular occlusion device teaches the use of tubular braids in medical devices providing reinforcing means to the wall of a guiding catheter, which may be adjusted as desired for a particular application by the pitch and pick of the fabric (Col. 3, lines 39-57; Col. 4, lines 11-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expandable housing portion of Hopkins to employ any well-known tubular braids doing so would have provided a means to reinforce the expandable housing portion. Further the teachings of Kelley teach the use of braids in varying braid pick counts vary the flexibility of the tubing (Col. 1, lines 40-67 and Col. 2, lines 1-15). Based on a standard dictionary definition of "flexible, Capable of being bent or flexed; capable of withstanding stress without structural injury: Pliable. "pliable" meaning, easily bent or shaped: Malleable, capable of being shaped or formed. Therefore, based on the teachings of braids of Kelley, the tubular braids of Amplatz could be adjusted to allow for expansion of the housing portion and therefore, would not interfere with the expansion of the housing portion, as one of ordinary skill in the art would know.

With respect to claim 4, Amplatz does not teach a plurality of reinforcing members. It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to have a plurality of reinforcing members, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). With respect to the non-woven note rejection of claim 3 above.

With respect to claim 5, Amplatz does not teach the reinforcing member extending substantially along the length of the expandable housing portion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member extending substantially along the length of the expandable housing portion, since it has been held that rearranging parts of an invention involves only routine skill in the art and applicant has not disclosed that having the reinforcing members extending substantially along the length of the expandable housing portion provides an advantage or solves a particular problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the reinforcing member positioned in any other arrangement of the housing portion because the housing portion would still be expandable. Therefore, it would have been an obvious matter of design consideration to modify Hopkin/Amplatz to obtain the invention as specified in claim 5.

With respect to claim 6, Amplatz teaches the reinforcing members are elongated bar-like members made from a material having a high stiffness (Col. 4, lines 11-65).

With respect to claim 7, Hopkins does not specifically disclose the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX. It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 9, Hopkins/Amplatz do not disclose/teach the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radiopaque bands (596, 598) providing a means so that positions of the bands relative to one another may be accurately determined. It would have been obvious to one of ordinary skill in the art to provide the reinforcing members with a material having high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

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With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claim 44, note rejection of claim 6 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

With respect to claim 51, the reinforcing members of Amplatz are fully capable of helping to bias the expandable housing portion in the contracted position based on the pitch and pick used (Col. 4, lines 10-65).

Response to Arguments

Applicant's arguments filed 6/19/06 have been fully considered but they are not persuasive. First with respect to the 112 first paragraph and the new matter of "non-woven" limitations previously presented. The examiner on page 13, of the previous office action stated, "...while applicant list materials in the specification for the reinforcing member, which may be non-woven, there is nothing in the specification which states the reinforcing members are non-woven, therefore this limitation is considered new matter. While a list of material may be non-woven, unless stated that the materials are non-woven, does not mean the materials are non-woven. Therefore the applicant needs to provide some evidence that the list of materials are non-woven. The 112 first paragraph rejection is being maintained by the examiner. As to the arguments that the Hopkins with Amplatz or Kelley patent works against the desired radial expandability of the housing, applicant is directed back to claim 3 above and Col. 4, lines 10-65 which teach NiTi which are very elastic they are said to be super elastic therefore does meet the limitations of the claim of providing column strength to the

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With respect to claim 10, note rejection of claim 7 above.

With respect to claims 11-13, note rejection of claim 5 above.

With respect to claim 20, Hopkins discloses an expandable housing portion (594) that includes a low expansion section with at least one expansion member (590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. ("low expansion section" is being considered by the examiner as a relative phrase, which the specification does not clearly define as to what constitutes a "low expansion section"). Also based on the teachings of Amplatz and the pitch and pick of the braid being adjusted as desired for a particular application it would have been obvious to one of ordinary skill in the art to have low expansion sections.

With respect to claim 21, note rejection of claim 4 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claim 25, note rejection of claim 4 above.

With respect to claim 26, Amplatz teaches reinforcing members (Col. 3, lines 39-57) which are fully capable of preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position because the reinforcing members provide strength which allowing for expansion.

With respect to claim 41, note rejection of claim 3 above.

With respect to claim 42, note rejection of claim 4 above.

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housing portion but not interfering with the expansion or contraction of the housing portion.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teena Mitchell
Teena Mitchell
Primary Examiner
Art Unit 3743
September 3, 2006

TKM
TKM



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994

24201 7590 01/04/2007
FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER
MITCHELL, TEENA KAY

ART UNIT PAPER NUMBER

3771

MAIL DATE DELIVERY MODE

01/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2 - MONTH RESPONSE DUE: _____

3 - MONTH RESPONSE DUE: _____

NOTICE OF APPEAL DUE:

(6-MONTH PERIOD ENDS)

March 11, 2007

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/897,295

Applicant(s)

BOYLE ET AL.

Examiner

Teena Mitchell

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

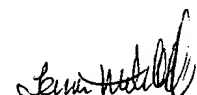
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112 first paragraph.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 3-13, 20-26 and 41-51.
Claim(s) withdrawn from consideration: 14-19 and 27-32.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.


Teena Mitchell
Primary Examiner
Art Unit: 3771

Continuation of 13. Other: Applicant's arguments are not persuasive the examiner maintains the previous rejection, note the Final Rejection at which time the arguments were addressed. .